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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Food and Drug Administration

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12 Sunnen Drive, Suite 122
St. Louis, Missouri 63143-3800
(314) 645-1167, (314) 645-2969 FAX

May 3, 1999

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Victor B. Lee
President
Fabulous Fish Co.
13560 N. W. Industrial Dr.
Bridgeton, MO 63044

Re: STL-99-02

Dear Mr. Lee:

An inspection of your firm on January 25 through 28, 1999, by a Food and Drug Administration Investigator from this office revealed the histamine-forming fish and molluscan shellfish are processed at, and distributed from, your facility under serious deviations from Title 21, Code of Federal Regulations (21 CFR), Part 123. These deviations cause these products to be adulterated under Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (The Act).

As we explained in a previous letter to your firm, the seafood processing regulations, which became effective December 18, 1997, require implementation of a preventive system of food safety controls known as Hazard Analysis Critical Control Point (HACCP). HACCP essentially involves: (1) identifying food safety hazards that, in the absence of controls, are reasonably likely to occur in your products; and (2) having controls at "critical control points" in the processing operation to eliminate or minimize the likelihood that the identified hazards will occur.

Our inspection revealed your processing of molluscan shellfish, tuna, and mahi-mahi deviates from the regulations contained 21 CFR Part 123 summarized as follows:

1. Failure to adequately apply appropriate corrective action(s) for refrigerated tuna as required by 21 CFR 123.7 (a)(2). For example, on the production cooler temperature record, dated 12/27, 28/1998, a beginning day hi/low temperature of [REDACTED] was recorded.
2. Failure to develop and implement a written HACCP Plan for molluscan shellfish as required by 21 CFR 123.6 (b).
3. Failure to list appropriate critical limit(s) that must be met at receiving and the production cooler storage critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the food safety hazard of histamine formation in your HACCP plan for refrigerated histamine-forming species. The temperature control provided in the HACCP plan does not provide adequate assurance that the hazard has been controlled. Therefore, it does not meet the requirement of 21 CFR 123.6(c)(3).
4. Monitoring record data for refrigerated tuna is missing. Examples are not all inclusive, included:
 - (i) On 11/3/98, no end of day cooler temperature data was recorded.
 - (ii) On 9/22/98, no beginning of day cooler temperature was recorded.
 - (iii) No documentation of the adequate cooling media critical limit was recorded for tuna received (For example: P.O. [REDACTED] and [REDACTED]).

This letter is not intended to be all-inclusive list of deficiencies at your facility. At the conclusion of the inspection you were issued a Form FDA-483, Inspectional Observations, which is a list of the investigator's observations of deviations noted during the inspection. It is your responsibility to ensure adherence to each requirement of the Act and regulations.

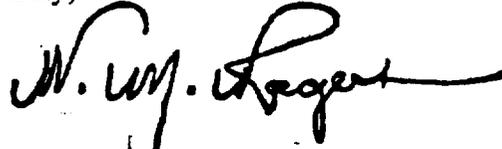
You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizure and/or obtaining a court injunction against further marketing of your seafood products.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you received this letter what steps you are taking to correct the problems. We also ask that you explain how you plan to prevent these violations from happening again. If you need more time, let us know why and when you expect to complete your correction.

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Your reply should be sent to Andrew H. Paeng, Compliance Officer, at the above address.

Sincerely,

A handwritten signature in black ink, appearing to read "W. Michael Rogers". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

W. Michael Rogers
District Director
Kansas City District